DENTINAL DESENSITIZING COMPOSITIONS

This is a division of application Ser. No. 08/167,558, filed Dec. 14, 1993, now U.S. Pat. No. 5,597,552, which is a continuation in part of application Ser. No. 07/811,811, filed Dec. 20, 1991, and now U.S. Pat. No. 5,270,031.

BACKGROUND OF THE INVENTION

Hypersensitive teeth can cause pain and discomfort when subjected to changes in temperature, pressure, or chemical action. Exposure of the dentin frequently leads to hypersensitivity. Dentin exposure may occur due to recession of the gums, periodontal disease and improper dental care. The usual method of treating hypersensitive teeth employs a desensitizing dentifrice or solution. Some of the active ingredients used in desensitizing dentifrices include strontium chloride, strontium acetate, potassium nitrate, and potassium chloride. Other treatments are applied professionally as a solution. These include solutions of ferric oxalate or potassium oxalate.

One approach to desensitization is to occlude exposed dentinal tubules. Dentinal tubules lead from the pulp to the surface of the dentin. When the surface of the tooth is eroded, the dentinal tubules become exposed to the external environment. The exposed dentinal tubules provide a pathway for transmission of fluid flow to the pulpal nerves and this is induced by changes in temperature, pressure and ionic gradients. By blocking the tubules, the external stimuli have a diminished effect, and less pain will be felt.

Some active ingredients, such as ferric oxalate, are known to form mineral deposits on the surfaces of exposed dentinal tubules, effectively blocking the openings. In some cases, the abrasive action from brushing may cause a smear layer to form over the surface of the tooth and thus plug up the open tubules. The accumulation of particulate matter from the interstitial fluid passing through the dentinal tubules or remineralization within the tubules can cause a natural occlusion of the tubules.

Nerve inactivation is another mechanism whereby desensitization can occur. This relies on the action of an active ingredient such as potassium nitrate on the nerves. By altering the ionic balance in the nerve, the threshold of nerve stimulation is increased. Thus a higher level of stimulation is needed to evoke a painful response.

The materials which have been used as active ingredients in the treatment of hypersensitive teeth are generally inorganic salts or hydrophobic compounds. Although hydrophilic polymers have been used in oral compositions as excipients or the like, they have not been suggested as being useful active ingredients for desensitization purposes. Most of the hydrophilic polymers have been used to control the viscosity of the oral formulation or to give it thixotropic properties.

An example of such a polymer is polyacrylic acid which is used as a thickener in dentifrice formulations. It has also been used in gels, mouthwashes and buccal adhesive patches. However, polyacrylic acid has also been used for other purposes. For example, Leonard et al. (U.S. Pat. No. 5,011,830) state an oral composition containing an alkali pyrophosphate salt, a fluoride salt and a polyacrylic acid or a copolymer of acrylic acid and another monomer can provide enhanced anti-calculus benefits. Gaffar (U.S. Pat. No. 3,956,480) uses an anionic polymer such as polyacrylic acid with chlorhexidine as an anti-calculus agent. Benedict and Sunberg (U.S. Pat. No. 4,661,341) describe the use of

polyacrylic acid or copolymers of polyacrylic acid as anti-calculus agents. In none of the examples above or elsewhere, as far as we are aware, are these polymers claimed to provide a desensitizing effect.

It has now been determined that certain water soluble or water swellable polyelectrolytes, i.e. polymers with functional groups that are capable of bearing one or more charged groups in an aqueous solution have desensitizing properties.

It is accordingly the object of this invention to provide new dentinal desensitizing agents. This and other objects of the invention will become apparent to those skilled in this art from the following detailed description.

SUMMARY OF THE INVENTION

This invention relates to an oral composition and method which is useful for relieving pain and discomfort caused by hypersensitive teeth. More particularly, the invention relates to the use of certain water soluble or water swellable polyelectrolyte partial salts as a dental desensitization agent. The cations used to make the salt can include ammonium, alkylammonium, calcium, sodium, potassium, strontium, magnesium, zinc, aluminum, tin, iron, barium, lanthanum, titanium, bismuth and copper. The salts may contain single cations or mixed cations.

The polymer and its salts may be formulated into a dentifrice, gel, buccal adhesive patch, mouthwash, lozenge, or gum. Use of these oral compositions on a regular basis can provide relief from the pain and discomfort of hypersensitive teeth. The oral composition described above may also provide for a sustained release mode of action for the delivery of strontium or potassium ions from the water soluble or water swellable polyelectrolytes. The polyelectrolytes may also be used in conjunction with additional desensitizing agents such as strontium chloride or potassium nitrate in an oral composition. In addition a source of fluoride ion can be incorporated into the composition.

DESCRIPTION OF THE INVENTION

In accordance with the present invention, a water soluble or water swellable polyelectrolyte partial salt is used as a dentinal desensitizing agent. The agent can be incorporated into a dentrifice, gel, mouthwash, lozenge, buccal adhesive patch, gum or the like. The water soluble or swellable polymer is an acrylic acid polymer (which term includes acrylic acid copolymers). Polyacrylic acid can be obtained, for instance, from B. F. Goodrich under the tradename Carbopol® or Noveon® as a cross-linked polyacrylic acid generically catagorized as carbomer or polycarbophil. Polyacrylic acid can also be obtained from Rohm and Haas under the tradename Acusol™.

The commercially available polymers are produced over a range of molecular weights. Thus, for instance, Carbopol® and Noveon® are available in different grades with different rheological properties. The different grades range in molecular weight from 450,000 (907 type) to 4,000,000 (980 type). It is preferable to employ the highest molecular weight grade consistent with the viscosity of the formulation being prepared and concentration of the agent. The formulations will contain a desensitizing amount which is generally from about 0.1% to 30% by weight of the polymer partial salt, with about 1–15% being preferred and about 2–12% most preferred. For any given concentration, viscosity generally increases with molecular weight and for any given molecular weight, viscosity generally increases with concentration.

The properties of the polyacrylic acid are modified to obtain the most advantageous properties by partial neutral-